

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE: :  
FOSAMAX PRODUCTS LIABILITY LITIGATION : 06 MD 1789 (JFK)  
-----:  
This document relates to: : OPINION AND ORDER  
Secrest v. Merck & Co., Inc., :  
No. 06 Civ. 6292 (JFK) :  
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APPEARANCES

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JOHN F. KEENAN, United States District Judge

**JOHN F. KEENAN, United States District Judge:**

This is the fourth case selected for trial as a bellwether in the In re Fosamax Products Liability Litigation multidistrict litigation ("Fosamax MDL"). The Fosamax MDL involves claims that Fosamax, a drug designed and produced by defendant Merck Sharp & Dohme Corp. ("Merck"), caused users of Fosamax to suffer from a condition known as osteonecrosis of the jaw. In this case, plaintiff Linda Secrest ("Secrest" or "Plaintiff") brings strict liability and negligence claims on theories of design defect and failure to warn, in addition to claims for fraudulent misrepresentation and concealment, and breach of warranty. Plaintiff also seeks punitive damages.<sup>1</sup>

Before the Court are four motions: (1) Merck's motion for summary judgment against Plaintiff on all claims; (2) Merck's motion to preclude Plaintiff's proposed expert testimony; (3) Plaintiff's motion to preclude Merck's proposed expert testimony; and (4) Merck's supplemental motion to preclude testimony of Dr. Epstein. For the reasons set forth below,

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<sup>1</sup> Frank Secrest, Linda Secrest's late husband, died on June 16, 2011. (Suggestion of Death, ECF No. 184, June 22, 2011.) Thereafter, Frank Secrest's claims were voluntarily dismissed pursuant to Rule 41 of the Rules of Civil Procedure. (Order of Dismissal with Prejudice, ECF No. 190, July 18, 2011.) In addition to the claims discussed herein, the Complaint filed in this case also contains a request for class certification, but the Court has denied similar motions for class certification in this MDL, see In re Fosamax Prods. Liab. Litig., 248 F.R.D. 389 (S.D.N.Y. 2008), and Plaintiff has not pursued these claims for purposes of this bellwether trial, so this request is denied.

Merck's motion for summary judgment is granted with respect to Plaintiff's claims for failure to warn, breach of warranty, fraudulent concealment, and punitive damages, but denied with respect to Plaintiff's claim for design defect. Merck's motions to preclude expert testimony are granted in part and denied in part. Plaintiff's motion to preclude expert testimony is granted in part and denied in part.

### **I. Background**

The following facts are taken from the parties' Local Rule 56.1 Statements, the declarations submitted in connection with the instant motions, and the exhibits attached thereto. Unless otherwise noted, the facts are undisputed.<sup>2</sup>

#### **A. Fosamax<sup>3</sup>**

Defendant Merck is a New Jersey-based pharmaceutical company that makes and distributes the drug alendronate sodium under the brand name "Fosamax." Fosamax belongs to a class of drugs called "bisphosphonates," which are commonly used to treat metabolic and oncologic diseases related to abnormalities in the

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<sup>2</sup> To the extent any sealed material is discussed herein, the information is hereby unsealed in light of the strong presumption of public access to judicial records.

<sup>3</sup> The Court discusses the development and characteristics of Fosamax only to the extent relevant to the instant motion. For further information on Fosamax, see In re Fosamax Products Liability Litigation, 645 F. Supp. 2d 164 (S.D.N.Y. 2009) (ruling on the parties' omnibus Daubert motions).

bone remodeling cycle. Fosamax is widely prescribed for the treatment and prevention of osteoporosis.<sup>4</sup>

The first generation bisphosphonates were developed in the 1960s and 1970s. The United States Food and Drug Administration ("FDA") approved Fosamax for the treatment of osteoporosis and Paget's disease in 1995 and for the prevention of osteoporosis in 1997. Fosamax was the first of three nitrogen-containing bisphosphonates approved for oral administration to treat these conditions.

Some users of bisphosphonate drugs have developed a rare condition called osteonecrosis of the jaw ("ONJ"). ONJ is characterized clinically by an area of dead jaw bone that becomes exposed to the oral cavity. Symptoms can include pain, swelling, and purulent secretion. The condition has been observed to develop after invasive dental procedures, such as tooth extractions, but has presented spontaneously in some cases.

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<sup>4</sup> "A person traditionally is diagnosed with osteoporosis when his or her bone mineral density ('BMD') is more than 2.5 standard deviations ('SD') below the mean for young adults of the same sex. This is referred to as a t-score of -2.5 SD." In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d at 169 n.2. However, prior to 2001 the National Osteoporosis Foundation Guidelines classified any t-score below -2.0 SD as indicating osteoporosis. See In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 269 n.5 (S.D.N.Y. 2009) (granting in part and denying in part Merck's motion for summary judgment in advance of the Boles bellwether trial).

ONJ can occur in the absence of bisphosphonate use, but its background rate in the population is not known. It has been reported to occur in connection with radiation therapy to the head and neck, osteomyelitis (inflammation/infection of bone marrow), osteopetrosis, herpes zoster virus infection, chemotherapy, and major trauma. The risk of developing ONJ is increased by factors such as periodontal disease, poor oral hygiene, and trauma. See In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d at 170.

Merck and Plaintiff disagree about when Merck received notice of the possible association between Fosamax use and ONJ. Plaintiff contends that Merck was put on notice of the possible association when it received reports from "over a hundred patients who had developed 'dental pain' and/or 'dental infection' during clinical trials in 1995." (Pl.'s Rule 56 Statement ¶ 6.) Plaintiff also contends that a number of adverse event reports ("AERs") received by Merck in the mid- and late-1990's mentioned "reaction terms selected by Merck for coding ONJ reports" and other "adverse oral outcomes." (Id. ¶ 7.) According to Plaintiff, these reports should have triggered additional investigation by Merck notwithstanding the fact that the reports did not specifically mention ONJ. Merck maintains that the AERs that did not explicitly mention ONJ were

insufficient to give notice of a possible association between Fosamax and ONJ.

It is undisputed that on October 3, 2003, Merck received for the first time an adverse event report expressly stating that a Fosamax patient had developed ONJ. Merck received two additional reports of ONJ in Fosamax users in January and March 2004. By April 2004, Merck had also been notified that Dr. Salvatore Ruggiero of the Long Island Jewish Medical Center in New Hyde Park, NY, was planning to publish an article in the Journal of Oral and Maxillofacial Surgery about sixty-three bisphosphonate patients who developed ONJ. Six of the patients in Dr. Ruggiero's study had taken Fosamax.

Merck alleges that these reports were reviewed by its Adverse Event Review Team ("AERT") in July 2004, and its Regulatory, Clinical, Epidemiology, Clinical Risk Management and Basic Research teams in September 2004. According to Merck, its various research teams at first recommended that it research the incidence rate of ONJ in Fosamax users. However, as additional reports of ONJ in Fosamax users came to Merck's attention in January 2005, its Label Evaluation and Development ("LEAD") Team recommended that Merck include a warning about these reports in the "Adverse Reactions" section of the Fosamax label.

Plaintiff challenges Merck's account of its reaction to the reports of ONJ, claiming that Merck's AERT recommended including

an ONJ warning in the Fosamax label as early as January 2004. Plaintiff bases this allegation on the October 22, 2010, deposition of Dr. Diane Benezra-Kurshan, a former member of the AERT. At this deposition, Dr. Benezra-Kurshan testified that the AERT first recommended inclusion of information about ONJ in the Fosamax label in January 2004. However, Merck, pointing to a statement made later in Dr. Benezra-Kurshan's deposition giving January 2005 as the date AERT first recommended including an ONJ warning on the Fosamax label, argues that Dr. Benezra-Kurshan was mistaken when she gave the earlier, January 2004 date.

It is undisputed that on January 31, 2005, Merck received a letter from the FDA requesting that Merck include the following precautionary language in the Fosamax label:

Osteonecrosis, primarily in the jaw, has been reported in patients treated with bisphosphonates. Most cases have been in cancer patients undergoing dental procedures, but some have occurred in patients with postmenopausal osteoporosis or other diagnoses. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids), and co-morbid disorders (e.g., anemia, coagulopathy, infection, pre-existing dental disease). Most reported cases have been in patients treated with bisphosphonates intravenously but some have been in patients treated orally.

For patients who develop osteonecrosis of the jaw (ONJ) while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring

dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

(Df.'s Decl. in Supp. of S.J. Mot., Ex. 31, Letter from David Orfloff to Merck 1.) This letter requested that Merck submit a revised label within six months. On March 1, 2005, Merck proposed different precautionary language, which it had been preparing prior to receiving the FDA's January 2005 letter. By letter dated June 21, 2005, the FDA requested that Merck use the exact language provided in its January 2005 letter.

Communications between Merck and the FDA continued, and on July 12, 2005, both Merck and the FDA agreed that the following language was appropriate for the Fosamax label:

Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates. Most reported cases of bisphosphonate-associated osteonecrosis have been in cancer patients treated with intravenous bisphosphonates, but some have occurred in patients with postmenopausal osteoporosis. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids), poor oral hygiene, and co-morbid disorders (e.g., pre-existing dental disease, anemia, coagulopathy, infection).

Patients who develop osteonecrosis of the jaw (ONJ) while on bisphosphonate therapy should receive care by an oral surgeon. Dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces

the risk for ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

(Df.'s Decl. in Supp. of S.J. Mot., Ex. 33, E-mail from Helen Durand, July 12, 2005.) This label was posted on Merck's website and distributed to physicians by sales representatives in August 2005. A number of additional revisions were made after the July 2005 label change, but these revisions are not relevant to this case.

**B. Linda Secrest's Fosamax Use and Medical Treatment**

Linda Secrest is a resident of Florida. She worked for United Airlines as a flight attendant for 34 years and at one point was based in San Francisco, California. At various times over the past thirty-nine years, Secrest's primary care physician was Dr. Lawrence Epstein, who practices medicine in Mountain View, California.

Secrest first used Fosamax in June 1998, and continued to use Fosamax until April 2005. Over this period of time, Secrest's bone density was measured several times. In June 1998, Ms. Secrest had a femoral neck (hip) t-score of -0.3 SD and a combined lumbar spine t-score of -2.26 SD. A scan taken in September 2001 showed that Ms. Secrest had a femoral neck (hip) t-score of -0.3 SD and a combined lumbar spine t-score of -1.8 SD. An additional scan taken in February 2005 showed that Ms. Secrest had a femoral neck (hip) t-score of -0.5 SD and a

combined lumbar spine t-score of -1.9 SD. (Pl.'s Rule 56.1 Statement ¶¶ 22-24.) These bone scans indicate that Ms. Secrest was osteopenic under current standards--and potentially at risk of developing osteoporosis--throughout the time she used Fosamax.

Dr. Epstein first prescribed Fosamax for Secrest in June 1998, but the parties dispute the precise amount and duration of Secrest's subsequent Fosamax use. Between June 1998 and April 2005, Secrest received Fosamax prescriptions from four different physicians: Drs. Epstein, Martin, Osborn, and Hidlebaugh. Dr. Epstein prescribed Fosamax to Secrest between June 1998 and March 2003, but according to Merck, Secrest had no Fosamax prescription during an eleven-month period between March 2000 and February 2001, a five-month period between early May 2001 and September 2001, a fifteen-month period between February 2002 and May 2003, or the period between late August 2003 and late December 2003. (See Df.'s Decl. in Supp. of Daubert Mot. Ex. 4.) Merck claims that the only prescription written by Dr. Osborn, one written in May 2002, was never filled by a pharmacy. (Df.'s Reply Mem. in Supp. Daubert Mot. 5 n.4.) Secrest claims that, according to her medical records, she used Fosamax continuously between May 1998 and April 2005, with the exception of a single four-month gap between September 2000 and January 2001. (See Pl.'s Mem. in Supp. of Daubert Mot. 11-15.)

This case primarily concerns the allegation that Secrest's use of Fosamax caused her to develop ONJ, but at various points in time, Secrest has suffered a number of other injuries in her jaw and oral cavity. Secrest suffers from xerostomia, or dry mouth; this placed her at a higher than average risk for infection in the oral cavity. In 2000, Dr. Marciano performed a number of dental implant surgeries on Secrest, in which five of thirteen dental implants failed to integrate. Secrest suffered from a tooth infection in April 2002 and a pseudomonas infection in December 2002, but these infections responded to treatment. (Marciano Dep. 27-28, 31-34, 37-38, 41-43.)

In her Plaintiff Profile Form ("PPF"), Secrest originally claimed an injury date of December 1999. However, Mrs. Secrest now alleges that she did not develop ONJ until March 2004. In March 2004, Secrest had an infection in the submental area of her jaw, which is "the area below [one's] chin." (Pl.'s Mem. Opp. Df.'s Daubert Mot. Ex. 3, 45:21-23.) Dr. Marciano tentatively diagnosed this infection as osteomyelitis but later referred Secrest to Dr. Marx because the suspected infection failed to respond to treatment. (Pl.'s Mem. in Opposition to Df.'s Daubert Mot. Ex. 3, Deposition of Dr. Marciano 62-63.) Dr. Marx later diagnosed Secrest's condition as ONJ with an associated infection secondary to Fosamax use. (Id. at 73.) Dr.

Marx recommended that Secrest stop taking Fosamax in April 2005, and her ONJ allegedly resolved by August 2005.

#### **C. Procedural History of this Case**

Plaintiff filed her complaint in the Middle District of Florida on April 10, 2006. On August 16, 2006, the Judicial Panel on Multidistrict Litigation designated this Court as the transferee forum for consolidated pretrial litigation of all federal court cases involving allegations that ingestion of Fosamax causes injurious side effects to the jaw, including osteonecrosis of the jaw, and transferred this case from the Middle District of Florida to this Court. See In re Fosamax Products Liability Litigation, 444 F. Supp. 2d 1347 (J.P.M.L. 2006). Pursuant to Fosamax MDL Case Management Orders 3, 9,<sup>5</sup> and 10, Merck and the Plaintiffs Steering Committee ("PSC") selected twenty-five cases to be worked up through expert discovery. This group of twenty-five cases, as modified, has served as the pool from which cases have been selected for bellwether trial. Originally, the Court and the parties contemplated holding three bellwether trials, but the total number was expanded to five on September 9, 2010, and this case was selected for trial on

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<sup>5</sup> There are two case management orders designated "No. 9" in the Fosamax MDL: one, dated January 3, 2007, deals with the handling of confidential information, while the other, dated January 30, 2007, deals with the selection of cases to be chosen for discovery and possibly for bellwether trial. Here, the Court refers to the latter case management order.

September 23, 2010. On February 4, 2011, the PSC and Merck were directed to select two additional cases, bringing the total number of bellwether trials in the Fosamax MDL to seven.

Pursuant to Case Management Order No. 3 and Case Management Order No. 8, each plaintiff in the Fosamax MDL has been required to complete a form referred to as a "Plaintiff Profile Form" or "PPF." Secrest completed her original PPF in February 2007, and later submitted a supplemental PPF in December 2010.

In advance of an anticipated trial date of March 14, 2011, the Court heard oral argument on February 15, 2011, concerning Merck's motion for summary judgment, Merck's Daubert motion concerning Drs. Marx and Marciano, and Secrest's Daubert motion. On March 1, Merck filed its Daubert motion concerning Dr. Epstein, and the Court granted Secrest's request for an adjournment of the trial.

On July 13, 2011, Mrs. Secrest filed the Third Supplemental Disclosures of Robert E. Marx, DDS, which notified the Court of articles published by Dr. Marx while the motions addressed herein were sub judice.

The trial in this case is now scheduled to begin on September 7, 2011.

**D. Proposed Expert Witnesses**

Each party moves under Rule 702 of the Federal Rules of Evidence and Daubert v. Merrell Dow Pharmas., Inc., 509 U.S. 579

(1993), to exclude certain expert testimony that the other party intends to present at trial. Merck seeks to exclude certain testimony of Drs. Robert Marx, Philip Marciano, and Lawrence Epstein, and Plaintiff seeks to exclude certain testimony of Drs. Norman Betts and Barry Gruber. Background on each of the proposed expert witnesses is provided below.

**1. Dr. Robert Marx**

Dr. Marx is a Professor of Surgery and the Chief of Oral and Maxillofacial Surgery at the University of Miami. In ruling on the parties' omnibus Daubert motions concerning general causation testimony, the Court found the testimony of Dr. Marx admissible under Rule 702 on the issue of general causation, In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d at 176, but later granted Merck's motion to exclude Dr. Marx from testifying "that Fosamax can cause [ONJ] before three years of continuous use," in part due to the discrepancy between his proposed testimony and the articles he has published on the subject. In re Fosamax Prods. Liab. Litig., No. 06 MD 1789, 2009 WL 2878439, at \*1 (S.D.N.Y. Sept. 9, 2009).

Dr. Marx has previously testified at bellwether trials in the Fosamax MDL. Now, as in prior bellwether trials, Dr. Marx states that he "no longer believe[s] that three years is an absolute threshold for the development of bisphosphonate-induced [ONJ]." (Id. at 3.)

In this case, Dr. Marx has opined that, based on his treatment of Secrest, Secrest suffered from "Stage 1 bisphosphonate-induced [ONJ] in or around mid-2004," that her use of Fosamax after mid-2004 continued to exacerbate her condition, and that her ONJ healed because she stopped taking Fosamax. (Df.'s Decl. in Supp. of Df.'s Daubert Mot., Ex. 14, Supp. Expert Discls. of Robert E. Marx, DDS Regarding Patient Linda Secrest ("Marx Supp. Discls.") 1-2.) Dr. Marx believes that Secrest continues to suffer from certain sequelae, or secondary effects, of bisphosphonate-induced ONJ, but notes that the worst ONJ symptoms have "abated." (Id. at 4.)

## **2. Dr. Philip Marciano**

Dr. Marciano is an oral surgeon licensed in Florida. As discussed above, Dr. Marciano treated Secrest for a condition he originally diagnosed as osteomyelitis and referred her to Dr. Marx after her infection failed to heal after a year of treatment. While Secrest claims that Dr. Marciano continued to treat her as a secondary physician after referring her to Dr. Marx, Dr. Marciano testified that he spoke with Dr. Marx about Secrest only once and did not perform any additional procedures. (Marciano Dep. 62:9-63:7.) Dr. Marciano has stated that he does not disagree with the diagnosis of ONJ made by Dr. Marx, and that he believes Fosamax was the "most likely factor" explaining

Secrest's injuries. (*Id.* 73:19-23; Mayer Decl. Ex. 19, 99:14-19.)

**3. Dr. Lawrence Epstein**

As mentioned above, Secrest has described Dr. Epstein as her primary physician of thirty years. Though he has treated Secrest for various ailments during that time, Dr. Epstein did not treat her alleged ONJ. Dr. Epstein will testify about Secrest's Fosamax use and his decision to prescribe Fosamax, but Secrest also intends to present expert testimony from Dr. Epstein about the import of the FDA's role in creating the Fosamax label, and about the "disappointing" results he has observed in his clinical experience.

Although Merck did not address possible expert testimony from Dr. Epstein in its original Daubert motion, Merck filed a supplemental Daubert motion addressing the admissibility of certain testimony from Dr. Epstein that Secrest intends to present at trial.

**4. Dr. Norman Betts**

Dr. Betts is a witness retained by Merck and is an oral and maxillofacial surgeon licensed in Michigan. There is no dispute about whether Dr. Betts is qualified to give testimony within the scope of Dr. Betts' expertise as an oral and maxillofacial surgery, and according to his expert report, Dr. Betts will opine at trial that "[t]here are no published, scientifically

valid studies showing an association between oral bisphosphonates and ONJ." (Pl.'s Mem. Supp. Pl.'s Daubert Mot. Ex. 1, at 4 (emphasis in original).)

**5. Dr. Barry Gruber**

Dr. Gruber is an expert witness retained by Merck, and is a board-certified rheumatologist. Merck intends to present Dr. Gruber as an expert on diseases of the bone, including osteoporosis, and to testify about the causal relationship between ONJ and Fosamax as well as the censoring of individuals from the Fosamax clinical trials who experience fracture. Dr. Gruber will testify that the censoring of certain individuals from the Fosamax clinical trials explains an apparent reduction in fracture efficacy that results from removing patients who suffered "adverse events" during those clinical trials.

**II. Discussion of the Parties' Motions to Preclude Expert Testimony**

Because the issue of what expert testimony is admissible bears on the Court's analysis of Merck's motion for summary judgment, the Court will first address the parties' motions to preclude expert testimony.

**A. Legal Standard**

The presentation of scientific and technical knowledge or opinion testimony by a "witness qualified as an expert" is

permitted under Rule 702 of the Federal Rules of Evidence where such testimony:

- (1) "is based upon sufficient facts or data;"
- (2) "is the product of reliable principles and methods;"
- (3) results from the reliable application of "principles and methods . . . to the facts of the case"; and
- (4) "will assist the trier of fact to understand the evidence or to determine a fact in issue."

Fed. R. Evid. 702. In fulfilling the "gatekeeping" function with which a district court is charged, "the district court should consider the indicia of reliability identified in Rule 702," specifically items 1-3 listed above. Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 265 (2d Cir.2002) (internal quotations omitted).

The requirement that expert testimony "assist the trier of fact" goes primarily to relevance. Daubert, 509 U.S. at 591, 113 S. Ct. at 2796. Helpfulness can be expressed as a question of "fit"--"whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Id. (quoting United States v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985)). In addition, expert testimony is not helpful if it simply addresses "lay matters which the jury is capable of understanding and deciding without the expert's help." United States v. Lumpkin, 192 F.3d 280, 289 (2d Cir. 1999). Finally, the testimony is not helpful if it "usurp[s] either the role of the trial judge in

instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it." United States v. Duncan, 42 F.3d 97, 101 (2d Cir. 1994) (quoting United States v. Bilzerian, 926 F.2d 1285, 1294 (2d Cir. 1991)).

The "reliable principles and methods" prong of Rule 702 analysis requires the Court to look to other factors in order to fulfill its designated "gatekeeping" role, such as:

- (1) whether a theory or technique has been or can be tested;
- (2) whether the theory or technique has been subjected to peer review and publication;
- (3) the technique's "known or potential rate of error" and "the existence and maintenance of standards controlling the technique's operation;" and
- (4) whether a particular technique or theory has gained general acceptance in the relevant scientific community.

United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007) (quoting Daubert v. Merrell Dow Pharmas., Inc., 509 U.S. 579, 593-94 (1993)). The purpose of analyzing proposed expert testimony in light of Rule 702 and the Daubert reliability factors is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152, 119 S. Ct. 1167, 1176 (1999). See Daubert v. Merrell Dow Pharmas., Inc., 509 U.S. 579, 592 (1993) ("Unlike an ordinary witness, an

expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. Presumably, this relaxation of the usual requirement of firsthand knowledge--a rule which represents a most pervasive manifestation of the common law insistence upon the most reliable source of information--is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.") (internal citations and quotations omitted).

**B. Dr. Robert Marx**

Merck moves to preclude any testimony by Dr. Marx that Fosamax caused Secrest to develop ONJ, as well as any testimony by Dr. Marx suggesting that placing a patient on Fosamax after an eleven- or twelve-month "drug holiday" immediately places a patient at risk of developing ONJ, that use of Fosamax "exacerbates" an existing ONJ, or that Secrest's ONJ would have been resolved sooner if she had stopped taking Fosamax earlier than she did. Merck also moves to preclude testimony from Dr. Marx suggesting that Secrest had "Stage Zero" ONJ or that Fosamax caused injuries other than ONJ.

**1. Specific Causation**

Merck seeks to preclude specific causation testimony from Dr. Marx on two separate but related grounds. First, Merck argues that Secrest did not use Fosamax continuously for three

years, and therefore Dr. Marx is not qualified to give specific causation testimony in this case. Second, Merck argues that, in forming the opinion that Secrest suffered from ONJ, Dr. Marx has incorrectly assumed that she used Fosamax for more than three years. For the reasons stated below, both of these arguments are rejected, and Dr. Marx may present his opinion that Fosamax caused Secrest's ONJ.

**i. Three-Year Use Issue**

Merck argues that the Court should disregard the mid-2004 injury date claimed in Secrest's supplemental PPF because she claimed an injury date of December 1999 in her original PPF. Merck's argument relies on the Court's ruling in the Graves v Merck & Co., Inc. bellwether case. In re Fosamax Prods. Liab. Litig., No. 06 MD 1789, 2010 WL 4242708 (S.D.N.Y. Oct. 27, 2010). In the Graves case, the Court held that the plaintiff could not alter her originally claimed injury date of March 2003 by arguing that no firm diagnosis of ONJ was made until November 2004. Id. at \*3; see In re Fosamax Prods. Liab. Litig., No. 06 MD 1789, 2010 WL 4273310, at \*7 (S.D.N.Y. Oct. 22, 2010). In ruling that the plaintiff in Graves could not alter her originally claimed injury date, the Court looked to both the plaintiff's PPF and her Rule 56.1 Statement, in which the plaintiff alleged the existence of the symptoms (particularly exposed bone) giving rise to her claim to have suffered from ONJ

as early as March 2003. In re Fosamax Prods. Liab. Litig., 2010 WL 4273310, at \*7.

This case is distinguishable from the Graves case for several reasons. The injury date stated in the original PPF is ambiguous with respect to whether December 1999 is claimed as the onset of ONJ. The PPF claims numerous injuries in addition to ONJ, including, for example, osteomyelitis, increased risk of developing ONJ, loss of dental implants, "inability to repair acceptable dental appliance," and constant jaw pain. (See Pl.'s Mem. in Opp. to Df.'s S.J. Mot. Exh. 19, at 3.) It is unclear whether the injury date of "12/99 - present" was intended to refer to some or all of the claimed injuries. The Court's ruling in Graves involved an unambiguous statement that the plaintiff began to suffer ONJ in March 2003.

Furthermore, the injuries referenced in Secrest's original PPF appear to be distinct from the symptoms of ONJ that Secrest allegedly suffered later which Dr. Marx relied on in diagnosing ONJ. Secrest does not base her claimed mid-2004 injury date on the date of her diagnosis, but instead offers expert testimony from Dr. Marx suggesting that she did not develop ONJ until mid-2004. (Pl.'s Mem. in Opp. to Df.'s S.J. Mot. Ex. 17, Deposition of Dr. Marx, at 17, 19, 63-65.) Whereas the plaintiff in Graves attributed her ONJ to symptoms that indisputably appeared as early as March 2003, Secrest does not rely on any of the medical

conditions she was experiencing in 1999 to prove that she later suffered from ONJ. In this case, it would not be appropriate to bar Secrest from offering evidence that she suffered from ONJ in mid-2004. Plaintiff has proffered sufficient evidence to suggest that there is a genuine dispute of fact regarding her date of injury.

Merck also argues that, even if Secrest is permitted to claim an injury date of mid-2004, she nonetheless did not use Fosamax regularly for three years prior to an alleged onset of ONJ because, according to her pharmacy records, at various times between 1998 and her claimed injury date of mid-2004, she did not have a valid prescription for Fosamax. To support her contention that she did use Fosamax continuously, Plaintiff refers to medical records indicating that she was using Fosamax at times when there are no pharmacy records, implying that the pharmacy records are incomplete. Merck contends that "medical records that reference Fosamax during the gaps identified by Merck cannot refute Plaintiff's pharmacy records showing that Plaintiff did not have Fosamax during those time frames." (Df.'s Reply Mem. in Supp. Daubert Mot. 5.)

Though Merck argues persuasively that the only proposed explanation for the gaps in pharmacy records put forth by Plaintiff in the course of this litigation--that certain prescription records were not maintained while others were--

would require the jury to make an inference about the possible disappearance of pharmacy records, the Court does not agree that this is such an "unreasonable inference" that no reasonable jury could find that Secrest used Fosamax continuously for three years prior to injury. It is undisputed that the medical records to which Secrest alludes support her contention that she used Fosamax regularly, with only a four-month gap. Merck urges the Court to assume that these medical records lack probative value simply because no corresponding pharmacy records have been located during discovery, but the Court cannot say that Secrest's medical records have no probative value on the issue of Secrest's Fosamax use, even if they are apparently contradicted by gaps in the pharmacy records. In this case, these medical records create a genuine dispute of fact regarding the duration of Secrest's Fosamax use.

Because a reasonable jury could find that Secrest used Fosamax regularly for three years, dismissal of Dr. Marx' testimony under Daubert is not appropriate. These rulings as to Dr. Marx do not preclude cross-examination by Merck as to the original PPF injury date of 1999 and the three year use issue.

#### **ii. Dr. Marx' Knowledge of Secrest's Fosamax Use**

Merck also moves to dismiss Dr. Marx' specific causation testimony, arguing that at his deposition, he did not know how long Secrest used Fosamax. However, the fact that Dr. Marx did

not appear to know the precise length of time Secrest used Fosamax does not make his testimony per se unreliable, because his opinion that Secrest suffered from ONJ as a result of using Fosamax was based on a number of available facts and his role as Secrest's treating physician. While Merck is free to cross-examine Dr. Marx about the accuracy of his conclusions at trial, the Court is unable to hold that Dr. Marx' opinion is inadmissible under Rule 702 and Daubert.

**2. Testimony Regarding Exacerbation or Delayed Healing of Secrest's ONJ**

To the extent that Merck challenges testimony from Dr. Marx regarding exacerbation or delayed resolution of Mrs. Secrest's ONJ as a result of ongoing Fosamax use, Merck's motion is granted because Dr. Marx does not express a non-speculative opinion. When deposed by Merck, Dr. Marx was asked: "What symptoms or problems did [Secrest] have that she would not have had if she had stopped Fosamax a year earlier?" To that question he responded: "Oh, I don't think anybody can tell, simply because who can predict the future or the past? [sic] It's a what-if question." (Marx Deposition Tr. at 109:19-24.) As Dr. Marx's response to this question reveals, his opinion regarding the tendency of continued Fosamax use to exacerbate ONJ cases is speculative and should be rejected as not being insufficiently "based on . . . facts or data." Fed. R. Evid. 702.

**3. Testimony Regarding "Stage Zero" ONJ**

Merck argues that because Dr. Marx cannot pinpoint an exact date on which Secrest developed "Stage Zero" ONJ, any opinion by Dr. Marx that Secrest had stage zero ONJ is inadmissible speculation. However, Merck has not shown that Dr. Marx used any unreliable methods in reaching the conclusion that Secrest suffered from Stage Zero ONJ at some point in time. Instead, in reaching this conclusion, Dr. Marx relied on his clinical experience. A failure to identify when a patient contracted a particular disease does not make testimony that a patient had that disease at some point in time inherently unreliable under Daubert.

**4. Concessions by Plaintiff**

To the extent that Merck moves to preclude testimony from Dr. Marx that Fosamax caused Secrest to experience delayed healing and the failure of bone grafts and dental implants, Mrs. Secrest does not oppose the motion. Secrest also concedes Merck's request to preclude Dr. Marx from testifying that use of Fosamax after a "drug holiday" immediately places the patient at risk of developing ONJ. Therefore, Merck's motion is granted on these grounds.

**C. Dr. Philip Marciano**

Merck seeks to preclude Dr. Marciano from offering specific causation testimony. In support of its motion, Merck argues

that Dr. Marciano's opinion testimony is based on "the false assumption that Plaintiff took Fosamax for six years prior to the onset of her injury," (Df.'s Mem. in Supp. of Df.'s Daubert Mot. 12), and that Plaintiff fails to address this argument in its opposition memorandum, (Df.'s Reply Mem. in Supp. of Df.'s Daubert Mot. 8).

Merck's motion to preclude specific causation testimony from Dr. Marciano is granted. Expert opinion is inadmissible under Rule 702 where such opinion testimony would not be helpful to the jury and where such opinion testimony is not based on reliable methods. Because the record indicates that Dr. Marciano's statement that Fosamax was the "most likely factor" causing Secrest's ONJ was based on hypothetical assumptions about Secrest's usage of Fosamax rather than concrete facts, and because the opinion Dr. Marciano offers is largely dependent on and derivative of Dr. Marx's opinions rather than any scientific inquiry conducted or treatment provided by Dr. Marciano himself, it is inadmissible under Rule 702.

**D. Dr. Lawrence Epstein**

Merck seeks to preclude Dr. Epstein from offering testimony about various topics, including the causation of Secrest's ONJ, a deposition of Merck employee Dr. Arthur Santora, a report prepared by FDA biostatistician Anthony Mucci, the alleged dangers of concomitant use of Fosamax and hormone replacement

therapy, the FDA's handling of Fosamax, and the efficacy of Fosamax in comparison to other osteoporosis medications. Merck also seeks to bar Dr. Epstein from testifying that Secrest did not have osteoporosis or that Fosamax has various harmful effects, offering calculations of Secrest's bone mineral density scores, or suggesting that Secrest used Fosamax for more than three years prior to 2004.

Plaintiff concedes that Dr. Epstein will not give general or specific causation testimony regarding Secrest's ONJ, and will not testify that Fosamax persists in the bone and causes harmful effects or bone fracture. Therefore, Merck's motion to preclude Dr. Epstein from offering such testimony on Daubert grounds is granted.

Because Dr. Epstein has conceded that he relied solely on other physicians to calculate Secrest's bone mineral density, Merck's motion to exclude his testimony regarding her bone mineral density on Daubert grounds is granted. Dr. Epstein may not offer testimony about the comparative efficacy of Fosamax to the drug Forteo, because he has not based this opinion on sufficient facts beyond his own clinical experience, and therefore such testimony could mislead the jury.

As a treating physician, Dr. Epstein is qualified to express certain opinions about his clinical experience with medical treatment options, including possible dangers of using

multiple drugs simultaneously, and making recommendations to patients. To the extent he has knowledge of the duration of Secrest's use of Fosamax, or an opinion about whether Secrest was correctly diagnosed as "osteoporotic" or "ostopenic," Dr. Epstein may testify regarding these topics, and Merck's motion to preclude testimony under Daubert is denied on these grounds.

Although Dr. Epstein may be qualified to express his opinion about the effect of certain label changes or additional warnings as a prescribing physician, the Court grants summary judgment in favor of Merck on Secrest's failure to warn claim below at p. 37. Therefore, testimony from Dr. Epstein concerning the Mucci Review, the FDA's role in the labeling process, or the definition of osteoporosis would not be relevant at trial, and Merck's motion to preclude this testimony under Daubert is moot.

**E. Dr. Norman Betts**

Mrs. Secrest seeks to preclude Dr. Betts from presenting various testimony under Rule 702 and Daubert, focusing on four discrete areas of possible testimony from Dr. Betts. Secrest seeks to preclude Dr. Betts from stating an opinion about the risks and benefits of Fosamax use, the background incidence rate of ONJ in patients who have not been on bisphosphonate drugs, or the use of CTX test results to determine risk or lack of risk for the development of bisphosphonate-related ONJ. Secrest also

argues that Dr. Betts should not be allowed to testify that Secrest had ONJ or osteomyelitis prior to the spring of 2004 or after 2005.

Merck does not oppose Secrest's motion to the extent it seeks to preclude Dr. Betts from testifying about the risk/benefit balance of Fosamax use or from stating an opinion about the relationship between risk of ONJ and CTX test levels. Therefore, Secrest's Daubert motion is granted on these unopposed grounds.

The Court denies Plaintiff's motion to preclude Dr. Betts from offering testimony about the "background rate" for ONJ in those who have not used bisphosphonate drugs, because Defendant has demonstrated that such testimony would be made with an adequate factual basis. Plaintiff does not dispute that the background rate for ONJ is unknown, and has introduced no contrary testimony suggesting that any statement proposed by Dr. Betts would be inaccurate.

Dr. Betts may also offer testimony about the date of onset of Secrest's injury. Plaintiff does not challenge the scientific reliability of Dr. Betts' (or other potential Merck witnesses') testimony on this topic. Instead, Plaintiff argues that Dr. Betts has made statements in the past that may contradict testimony that Secrest had ONJ prior to spring 2004 or after 2005. To the extent that these prior statements call

into question any testimony introduced by Dr. Betts at trial, Plaintiff will have the opportunity to cross-examine Dr. Betts about these prior statements. However, a jury would not necessarily have to accept Plaintiff's characterization of Dr. Betts' prior statements as contradicting testimony about possibly earlier or later onset of Secrest's injuries.

**F. Dr. Barry Gruber**

Secrest moves for an order precluding Dr. Gruber from presenting an opinion about the causal relationship between bisphosphonate drugs and ONJ and from testifying that Secrest had glucocorticoid-induced osteoporosis, a condition that arises when the use of certain steroid drugs degrades bone density. Finally, Secrest argues that Dr. Gruber should be barred from presenting testimony about the censoring of patients with fractures from Fosamax clinical trials.

Merck does not intend to present testimony from Dr. Gruber suggesting that Secrest has glucocorticoid-induced osteoporosis, and therefore Secrest's Daubert motion is granted on his ground.

Merck opposes Secrest's motion with respect to Dr. Gruber's ability to present testimony about the causal relationship between Fosamax and ONJ. Although it is true that a "scientist . . . is not permitted to be the mouthpiece of a scientist in a different specialty," Dura Automotive Systems, 285 F.3d at 614, the Court has previously noted that specialization in oral or

maxillofacial surgery is not the only way to become familiar with issues relating to the treatment of bone diseases.

Therefore, Dr. Gruber may express his opinion about the causal relationship between Fosamax and ONJ so long as he bases this opinion on his experience as a rheumatologist.

Finally, Plaintiff argues that, because Dr. Gruber was unable to confirm that patients were "censored out" of the clinical trials during his deposition, his opinion lacks a sufficient factual basis. In opposing Secrest's Daubert motion to preclude Dr. Gruber from testifying about the exclusion of certain patients from Fosamax clinical trials, Merck identifies two factual bases for Dr. Gruber's understanding that high-risk patients were "censored out" of the clinical trials: (1) a 2009 article by E. Seeman, published in Osteoporosis International; and (2) the FIT protocol, which Merck contends was not shown to Dr. Gruber at his deposition. These documents provide a sufficient basis for Dr. Gruber's opinion that censoring of patients over time caused apparent reductions in efficacy after 36 months because medical doctors and scientists have, in fact, regularly relied on similar journal publications and trial protocols when assessing the results of studies during the course of the Fosamax MDL. Therefore, given these factual bases, Dr. Gruber's testimony on this topic will be helpful to the jury.

### **III. Discussion of Merck's Motion for Summary Judgment**

Merck moves for summary judgment with respect to all claims because Plaintiff has failed to present adequate evidence that Fosamax caused Linda Secrest's injuries. Merck also moves for summary judgment with respect to Plaintiff's failure to warn, fraudulent misrepresentation, breach of warranty, and punitive damages claims on various other grounds.

#### **A. Legal Standard**

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" if, on the evidence relevant to that dispute, "a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is "material" if it "might affect the outcome of the suit under the governing law." Id.

In determining whether there is a genuine issue of material fact, "courts must resolve all ambiguities, and credit all factual inferences that could rationally be drawn, in favor of the party opposing summary judgment." Roe v. City of Waterbury, 542 F.3d 31, 35 (2d Cir. 2008). A district court is not, however, required to engage in speculation on behalf of the non-moving party. "The movant has the burden of showing that there is no genuine issue of fact, but the plaintiff is not thereby

relieved of his own burden of producing in turn evidence that would support a jury verdict. Rule 56[(c)(1)] . . . provides that a party opposing a properly supported motion for summary judgment may not rest upon mere allegation or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." Liberty Lobby, 477 U.S. at 256.

**B. Specific Causation Issue**

Merck claims entitlement to summary judgment on all of Secrest's claims because she has failed to offer admissible expert testimony that Fosamax proximately caused her ONJ. This argument relies on the assumption that the testimony of both Drs. Marciano and Marx would be precluded through Merck's Daubert motion. However, because the Court has denied Merck's Daubert motion with respect to specific causation testimony from Dr. Marx, there is a genuine dispute of fact on the issue of specific or proximate causation, and the Court denies Merck's motion for summary judgment on these grounds.

**C. Strict Liability and Negligent Failure to Warn Claims**

Merck argues that it is entitled to summary judgment on Plaintiff's negligent and strict-liability failure to warn claims because Plaintiff has not presented evidence that Dr. Hidlebaugh, Secrest's prescribing physician at the time of her injury would have changed his decision to prescribe Fosamax if Merck had given a different warning about the risk of ONJ.

Secrest argues that there is sufficient evidence to support a failure to warn claim because Dr. Epstein has testified that if Merck had informed him that Fosamax posed a risk of ONJ, then as her prescribing physician, he would have recommended that Secrest stop taking Fosamax.

Under Florida law, a manufacturer of a product has a duty to warn of all non-apparent "scientifically discoverable dangers," even if that manufacturer does not have "actual knowledge" of a particular danger. Carter v. Brown & Williamson Tobacco Corp., 778 So. 2d 932, 942-943 (Fla. 2000). When a manufacturer has a duty to warn, "[s]trict liability and negligent failure to warn cases boil down to three elements that Plaintiff must prove: 1) that the warnings accompanying the item were inadequate; 2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and 3) that Plaintiff in fact suffered an injury by using the product." Colville v. Pharmacia & Upjohn Company LLC, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (citations omitted). Because it is an essential element of both strict liability and negligent failure to warn claims, a plaintiff cannot maintain a failure to warn claim without proving that the failure proximately caused his or her injury. See Alvarez v. Gen. Wire Spring Co., No. 8:07-cv-1319, 2009 U.S. Dist. LEXIS 6878, at \*23 (M.D. Fla. Feb. 1, 2009).

"One method of negating proximate cause is for the defendant to demonstrate that even an adequate warning would not have altered the particular plaintiff's course of conduct."

Stanley Indus., Inc. v. W.M. Barr & Co., 784 F. Supp. 1570, 1574 (S.D. Fla. 1992). Since drug manufacturers have a duty to warn the prescribing physician rather than the patient under the "Learned Intermediary Doctrine," see Buckner v. Allergan Pharmas., 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981), it is the prescribing physician's course of conduct that is most relevant to proximate cause in the prescription drug context, see also In re Fosamax Prods. Liab. Litig., 06 MD 1789, 2010 WL 1257299 (S.D.N.Y. March 26, 2010). Though a prescribing physician's course of conduct is the most directly relevant issue, other courts have recognized that proximate causation can be satisfied for purposes of the Learned Intermediary Doctrine where a non-prescribing physician testifies that the physician was aware of the patient's use of a given drug and would have recommended taking the patient off of that medication if a different warning had been given. See Golod v. La Roche, 964 F. Supp. 841, 857 (S.D.N.Y. 1997).

In this case, Dr. Epstein has testified that he was "not aware . . . that [Dr.] Hidlebaugh was prescribing Fosamax to Secrest between 2004 and 2005." (Epstein Aug. 8, 2008, Deposition Tr., at 47:4-7.) Although at a later deposition

conducted in February 2011, Dr. Epstein was asked if he knew Secrest was on Fosamax between 2004 and 2005 and Dr. Epstein initially responded that he "knew she was on it," at the very same deposition, Dr. Epstein admitted that he was basing this new testimony on prescription records, rather than personal knowledge, and that he "assumed she was [taking Fosamax at the time in question], but [had] no concrete evidence." (Epstein Feb. 11, 2011, Deposition Tr., at 114-15.) This suggests that when Dr. Epstein testified he knew that Secrest was taking Fosamax between 2004 and 2005, he was making an assumption, rather than testifying about what he knew at the relevant times.

In this case, there is no admissible evidence from which a reasonable jury could conclude that Dr. Epstein was aware that Secrest was on Fosamax between 2004 and 2005, and the assertion that Dr. Epstein would have warned her to stop taking Fosamax if Merck had included a warning on its label is purely speculative. Plaintiff has failed to show that a different warning would have prevented her prescribing physician from keeping her on Fosamax at the time of her alleged injury, and therefore Merck is entitled to summary judgment on Merck's failure to warn claim.

#### **D. Punitive Damages**

Merck argues that Plaintiff has failed to present evidence adequate to support a claim for punitive damages. Florida's statute governing punitive damages reads, in relevant part:

A defendant may be held liable for punitive damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence. As used in this section, the term:

(a) "Intentional misconduct" means that the defendant had actual knowledge of the wrongfulness of the conduct and the high probability that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage.

(b) "Gross negligence" means that the defendant's conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct.

Fla. Stat. § 768.72(2); see In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 283 n.11 (S.D.N.Y. 2009) (finding that Fla. Stat. § 768.72 "is clear enough on its face to be applied without turning to potentially superseded case law for interpretive assistance").

In prior bellwether cases, this Court has granted summary judgment in favor of Merck with respect to the plaintiffs' claims for punitive damages because, given the evidence proffered by the plaintiff, "[n]o jury could reasonably find by clear and convincing evidence that Merck's actions rose to the level of intentional misconduct," and that plaintiff failed to produce any "evidence--let alone clear and convincing evidence--that Merck had 'actual knowledge' of the 'high probability' that Fosamax" could cause users to develop ONJ. In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 284 (S.D.N.Y. 2009). Those

prior cases involved injury dates prior to October 2003, whereas Secrest claims she developed ONJ later, in mid-2004. Therefore, Secrest attempts to distinguish her case from previous bellwether trials based on additional information that became available to Merck in between October 2003 and mid-2004.

Although Plaintiff correctly points out that prior to her injury date, the information available to Merck consisted of more than a "handful of exostosis reports," see id. at 284, Plaintiff has failed to introduce any evidence suggesting that Merck acted in a grossly negligent fashion in response to the available information. Rather than offering "clear and convincing evidence" that Merck reacted to the information that became available between October 2003 and her injury date in an intentionally wrongful or grossly negligent fashion, Plaintiff asserts in a conclusory fashion that, given the information available, Merck had a duty to add a warning about a possible connection between Fosamax and ONJ to the Fosamax label, and that its breach of this duty constitutes gross negligence.

Plaintiff's reliance on Dr. Beneza-Kurshan's testimony that Merck's AERT recommended inclusion of an ONJ warning on the Fosamax label in January 2004 is misplaced because, even if this recommendation was made in January 2004 rather than a year later as Dr. Beneza-Kurshan has since testified, Plaintiff has offered no evidence suggesting that Merck engaged in intentionally

wrongful or grossly negligent conduct by delaying a label change until it had worked out language with the FDA.

To recover punitive damages in the context of a products liability action, a plaintiff must show not only that the manufacturer breached a legal duty, but also that the manufacturer did so intentionally or out of a "conscious disregard or indifference" to the well-being of its customers. On the evidence presented by Plaintiff, no reasonable jury could conclude that Plaintiff would be entitled to punitive damages. Therefore, the Court grants Merck's motion for summary judgment with regard to Plaintiff's claim for punitive damages.

**D. Fraudulent Misrepresentation Claim**

Merck moves for the dismissal of Plaintiff's claim for fraudulent misrepresentation. There are four essential elements of a fraudulent misrepresentation claim under Florida law: "(1) a false statement concerning a material fact; (2) the representor's knowledge that the representation is false; (3) an intention that the representation induce another to act on it; and (4) consequent injury by the party acting in reliance on the representation." Butler v. Yusem, 44 So.3d 102, 105 (Fla. 2010); see also Jones v. General Motors Corp., 24 F. Supp. 2d 1335, 1339 (M.D. Fla. 1998) (citations omitted). In a products liability suit concerning pharmaceuticals, an injured plaintiff can maintain a suit for fraudulent misrepresentation against the

manufacturer of a drug where he can show that the manufacturer has "fraudulently misrepresent[ed] or conceal[ed] the risk of a drug to [the plaintiff's prescribing physician]." In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d at 283.

In this case, Plaintiff--referring to a report prepared by Anthony Mucci--contends that Merck intentionally defrauded Dr. Epstein when its sales representatives expressed their belief that "Fosamax would assist with reducing fractures in patients without osteoporosis, like Linda Secrest, when in fact the FDA found no fracture reduction in any patient whose bone density T-score was already better than -2.5." (Pl.'s Mem. in Opp. to Merck's S.J. Mot. 25.) However, Plaintiff fails to allege that Merck was aware of the FDA report, or the information contained therein, that forms the basis for Plaintiff's allegation that Merck misstated the risk/benefit profile of Fosamax. Because Plaintiff has not offered any evidence that Merck willfully defrauded Dr. Epstein, the Court grants summary judgment in favor of Merck with respect to Plaintiff's fraudulent misrepresentation claims.

**F. Breach of Warranty**

Plaintiff does not oppose Merck's motion for summary judgment with respect to its implied and express warranty claims, and therefore Merck's motion for summary judgment is granted with respect to these claims.

**IV. Conclusion**

For the reasons stated above, Merck's motion for summary judgment is granted with respect to Plaintiff's claims for failure to warn, breach of warranty, fraudulent concealment, and punitive damages, but denied with respect to her design defect and claim.

Merck's motions to preclude expert testimony and Plaintiff's motion to preclude expert testimony are each granted in part and denied in part.

**SO ORDERED.**

Dated: New York, New York  
August 30, 2011

  
JOHN F. KEENAN  
United States District Judge